

09/730334



SPINAL FLUID COLLECTION SYSTEM

BACKGROUND

A spinal tap is a procedure which takes samples of a patient's cerebrospinal fluid (CSF). Spinal taps are performed when the physician suspects that the patient may have bleeding (such as subarachnoid hemorrhage) or an infection of the central nervous system (such as meningitis or encephalitis). These procedures are often performed in the emergency room but are also performed in a doctor's office or in a hospital setting.

Usually, before beginning a spinal tap procedure, the physician, or another medical professional arranges the contents of a spinal tap "kit" on a tray, positioned next to where the physician will be sitting to perform the procedure. The "kit" usually consists of four sterile tubes, a spinal needle (with a stylet inserted through the spinal needle), along with items for sterilizing the patient's skin and draping the patient. Sometimes a test tube rack to hold the tubes is also positioned on the tray. Before the procedure, the physician or another medical professional removes all of these items from their sterile packaging, unscrews the caps from the tubes, and arranges everything on the tray for easy access during the procedure.

Usually, the patient is asked to lie down in a curled-up position, exposing the back. The physician then sterilizes the patient's back and numbs the skin around the insertion point. In

1 RECEIVED
JUN 06 2002
2 TC 1700

other words, the physician or other medical professional does a "sterile prep and drape." The physician then inserts a spinal needle, with a stylet inside the spinal needle, between the patient's vertebrae (usually in the L3-4 or L4-5 interspace) and advances the needle until the needle has reached the fluid-filled area surrounding the patient's spine, the dural space. The stylet is used to prevent the tip of the spinal needle from becoming blocked by tissue as the needle is inserted through the patient's skin and other tissues. Once the needle is in place, the stylet is removed from the spinal needle and usually placed on the sterile tray. CSF flows through the needle and drips from the proximal end of the needle. The physician then takes four sterile tubes (three for pediatric patients) in turn from the tray and fills the tubes each with approximately 1 ml (or 1 cc) of CSF.

Usually, the physician must reach for a (closed or open) tube on the tray, collect an appropriate amount of CSF in the tube, seal the cap onto the tube (so that the fluid does not spill), reach over to the tray, lay the tube down on the tray, pick up another tube from the tray and repeat the process. If the physician is using a test tube rack, the physician must take an open tube from the test tube rack, collect an appropriate amount of CSF in the tube, replace the tube into the test tube rack on the tray, pick the next open tube from the test tube

rack, and repeat the process. Currently, each test tube itself must be held beneath the proximal end of a spinal needle as the spinal fluid is collected. Space is tight between the physician and the patient with a spinal needle protruding from his/her back.

Once collected, CSF is then sent to a laboratory to determine if the patient is suffering from viral (for example, Enteroviruses and Herpes viruses, as well as Arboviruses, Rabies or measles among other viral agents), bacterial (including *Haemophilus influenza*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, and also *Listeria monocytogenes*, *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Mycobacterium tuberculosis*, *Escherichia Coli* or other Gram negative enteric bacteria) or fungal (including *Cryptococcus neoformans*, *Coccidioides immitis*, among other fungal agents) infection of the brain or supporting structures, among other possible diagnoses. The CSF is also examined for white and red blood counts and chemical components.

This procedure is very uncomfortable for the patient. The procedure is especially uncomfortable if the patient is very young or very sick, which is often the case. Reducing the duration of this procedure would reduce the duration of the patient's discomfort. This procedure also represents significant risk to the patient. Time is ticking while the physician puts the stylet down on the tray, reaches for a test tube, places the

test tube in the proper position to collect CSF, fills the tube, screws the cap back on and reaches for the next tube. All the while, CSF is flowing from the patient. Patients may develop severe side effects from the loss of too much CSF, including severe headaches. The risk of the patient moving and causing injury exists for the duration of the procedure. These risks include a risk of lacerating a spinal nerve, lacerating the meninges (causing permanent or persistent leaks of CSF), or bleeding, which complicates the interpretation of laboratory results. These risks are increased in very young patients who are more likely to move during the procedure. In addition, there is a risk of respiratory arrest in neonates who are held in a curled-up position for the duration of the procedure. Reducing the duration of this procedure reduces these risks. In addition, these procedures are often performed in emergency rooms where physician time is at a premium. Minutes shaved from a procedure, performed several times over the course of a shift, may result in the physician being able to tend to additional patients.

OBJECTS

It is a primary object and feature of the present invention to provide a cerebrospinal fluid collection system which allows a physician to better prepare for a spinal tap procedure, reduce the time necessary to carry out a spinal tap procedure, and reduce the risk of injury and severe side affects related to

spinal tap procedures. It is a further object and feature of this invention to provide a test tube rack which is not too bulky, too difficult to hold, and/or too unwieldy to be used to hold test tubes while CSF is being collected. It is a further object and feature of the present invention to provide a test tube rack which is inexpensive to manufacture, disposable, sterilizable, see-through and lightweight. Other objects and features of this invention will be shown by the following descriptions and claims.

SUMMARY

According to a preferred embodiment of the present invention, this invention provides a spinal fluid collection system for use by a medical professional for collecting, from a spinal tap into a plurality of CSF tubes, multiple samples of cerebrospinal fluid from a patient, comprising, in combination: a plurality of CSF tubes structured and arranged to receive, seal, and transport cerebrospinal fluid; at least one spinal tap assembly structured and arranged to tap into the patient to obtain a flow of cerebrospinal fluid; and a holder structured and arranged to stably hold such CSF tubes when such holder is in an upright position; wherein such holder comprises a handle structured and arranged to assist single-hand manipulation of such holder by the medical professional during the collecting of the cerebrospinal fluid directly from such spinal tap into such

CSF tubes, when held by such holder, in a continuing manner without the need to grasp any such CSF tube during the collecting. It also provides such a system further comprising a sealed internally-sterile package sealing such holder and such CSF tubes. And wherein such package further seals at least one such spinal tap assembly; and further, wherein such handle is structured and arranged to be grasped by either a right hand or a left hand of the medical professional.

Additionally, it provides such a system wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, any element selected from the group consisting of a spinal needle, a spinal needle sleeve, a spinal needle stylet, a spinal needle sleeve holding a spinal needle, a spinal needle sleeve holding a spinal needle and a stylet.

It also provides such a system wherein such holder is structured and arranged to stably hold four of the CSF tubes when such holder is in an upright position; wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a first portion of such holder any such element selected from such group; and wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a second portion of such holder any such element selected from such group. And it further provides such a system wherein such holder further comprises four first vertical

cavities each structured and arranged to support one of the CSF tubes; and at least two second vertical cavities each structured and arranged to support any such element selected from such group.

Moreover, it provides such a system wherein such holder comprises an essentially-transparent plastic material. It also provides such a system wherein such handle is structured and arranged to be grasped by either a right hand or a left hand of the medical professional. And it provides such a system wherein such first and second vertical cavities are arranged along a horizontal longitudinal row, having a midpoint, of such holder; and such handle is essentially horizontal and symmetrical with respect to such midpoint. And it further provides such a system wherein such handle comprises the furthest longitudinal horizontal extensions of such holder.

According to a preferred embodiment of the present invention, this invention also provides a spinal fluid collection system for use by a medical professional for collecting, from a spinal tap into a plurality of CSF tubes, multiple samples of cerebrospinal fluid from a patient, comprising: a holder structured and arranged to stably hold the CSF tubes when such holder is in an upright position; wherein such holder comprises a handle structured and arranged to assist single-hand manipulation of such holder by the medical professional during the collecting

of the cerebrospinal fluid directly from the spinal tap into the CSF tubes, when held by such holder, in a continuing manner without the need to grasp directly any of the CSF tubes during the collecting; and wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, any element selected from the group consisting of a spinal needle, a spinal needle sleeve, a spinal needle stylet, a spinal needle sleeve holding a spinal needle, a spinal needle sleeve holding a spinal needle and a stylet. Further, it provides such a system wherein such holder is structured and arranged to stably hold four of the CSF tubes when such holder is in an upright position; wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a first portion of such holder any such element selected from such group; and wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a second portion of such holder any such element selected from such group. And also, wherein such holder further comprises four first vertical cavities each structured and arranged to support one of the CSF tubes; and at least two second vertical cavities each structured and arranged to support any such element selected from such group.

Still further, it provides such a system wherein such holder comprises an essentially-transparent plastic material. And even

further, it provides such a system wherein such handle is structured and arranged to be grasped by either a right hand or a left hand of the medical professional. Also, it provides such a system wherein such first and second vertical cavities are arranged along a horizontal longitudinal row, having a midpoint, of such holder; and such handle is essentially horizontal and symmetrical with respect to such midpoint. And it provides such a system wherein such handle comprises a horizontal plate comprising the furthest horizontal extensions of such holder in at least two directions; and wherein such handle comprises the furthest longitudinal horizontal extensions of such holder.

According to another preferred embodiment of the present invention, this invention also provides a spinal fluid collection system for use by a medical professional for collecting, from a spinal tap into a plurality of CSF tubes, multiple samples of cerebrospinal fluid from a patient, comprising the steps of: providing a CSF-tube holder having a handle and needle-holder to stably hold a spinal needle assembly; arranging at least three open CSF tubes in such holder; inserting a spinal needle containing a stylet between a patient's vertebrae until a tip of the spinal needle reaches a dural space; removing such stylet from such spinal needle; placing such stylet in such needle-holder of such holder; grasping such holder by such handle; placing such holder under the proximal end of such spinal needle

so that CSF drips from such proximal end of such spinal needle into a first such open test tube; determining when such first open test tube contains a sufficient amount of CSF; shifting such holder so that CSF drips from such proximal end of such spinal needle into a second such open test tube; determining when such second open test tube contains a sufficient amount of CSF; shifting such holder so that CSF drips from such proximal end of such spinal needle into a third such open test tube; determining when such third open test tube contains a sufficient amount of CSF; removing such stylet from such needle-holder; replacing such stylet inside such spinal needle; removing such spinal needle containing such stylet from the dural space; placing such spinal needle containing such stylet into such needle-holder; and closing such three open test tubes.

Further it provides such a system further comprising the steps of: placing a needle sleeve into such needle-holder of such holder; and placing such spinal needle containing such stylet into such needle sleeve.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a preferred embodiment of the spinal fluid collection system of the present invention, and further illustrating a hand holding such system.

Fig. 2 is a top view of the test tube rack of the preferred embodiment of Fig. 1.

Fig. 3 is a front view of the preferred embodiment of Fig. 1, but illustrating the test tube rack holding four tubes, a needle in its needle sleeve and a stylet.

Fig. 4 is a partial front view of the preferred spinal fluid collection system, illustrating the first step in the method of using such system, assembling the equipment.

Fig. 5 is a pictorial view illustrating a subsequent step, inserting the spinal needle into a back.

Fig. 6 is a partial close-up view illustrating a subsequent step, removing the stylet from the needle.

Fig. 7 is a partial perspective view illustrating a subsequent step, collecting CSF into a tube held in the test tube rack.

Fig. 8 is a partial front view illustrating an additional step, collecting CSF into another tube held in the test tube rack.

Fig. 9 is a front view illustrating an additional step, collecting CSF into a final tube held in the test tube rack.

Fig. 10 is a front view illustrating an additional step, closing the tubes and replacing the needle into the rack.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS AND BEST MODES OF PRACTICE

Fig. 1 is a perspective view of a preferred embodiment of the present invention illustrating a hand **20** holding the system

19, which embodies herein a spinal fluid collection system for use by a medical professional for collecting, from a spinal tap into a plurality of CSF tubes, multiple samples of cerebrospinal fluid from a patient. Illustrated in Fig. 1 is a preferred embodiment of the test tube rack **21**, embodying herein a holder structured and arranged to stably hold such CSF tubes when such holder is in an upright position. The test tube rack **21** is preferably made of clear (i.e. see-through), lightweight, sterilizable, disposable, medical-grade plastic material. The test tube rack **21** has a top shelf **22**, a handle shelf **40**, a bottom shelf **41**, an inside shelf **42**, two side panels **37**, and two open sides **35**.

Top shelf **22** preferably has four test tube holes **23** arranged in a row across top shelf **22**. These test tube holes **23** are preferably just slightly larger than the outside diameter of the test tubes **24** so that the test tubes **24** easily slide through the test tube holes **23** in top shelf **22** but also restrict the movement of the test tubes **24** within the test tube holes **23**. The inside shelf **42** also preferably has four test tube holes **23**, sized to contain test tubes **24**, arranged in a row across inside shelf **42**, and aligned directly below the four test tube holes **23** in top shelf **22**. Preferably, each test tube **24** (embodying herein a plurality of CSF tubes structured and arranged to receive, seal, and transport cerebrospinal fluid) can slide through one of the

four test tube holes **23** in the top shelf **22**, slide through the corresponding test tube hole **23** in the inside shelf **42**, and come to rest against bottom shelf **41** (which preferably does not have holes but which may have indentations if desired to assist stabilizing test tubes resting in the rack).

Also illustrated in Fig. 1 are needle holes **25**, preferably arranged with one needle hole **25** at each end of the row of four test tube holes **23** in top shelf **22**, this arrangement embodying herein a holder wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a first portion of such holder any such element selected from such needle assembly group; and wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, at a second portion of such holder any such element selected from such group. And this arrangement further embodies wherein such holder further comprises four first vertical cavities each structured and arranged to support one of the CSF tubes, and at least two second vertical cavities each structured and arranged to support any such element selected from such needle assembly group. Preferably, inside shelf **42** also has two needle holes **25** arranged directly underneath the needle holes in top shelf **22** so that a spinal needle **26**, or a stylet **28**, or a needle sleeve **27**, or any combination of these, can preferably slide through the needle hole **25** in the top shelf **22**, slide

through corresponding needle hole **25** in the inside shelf **42**, and come to rest against the bottom shelf **41**.

Preferably, bottom shelf **41** has a slight indentation **44** (see Fig. 7) in its inside surface **54** (see also Fig. 7), aligned directly underneath the needle hole **25** in inside shelf **42** and top shelf **22** so that spinal needle **26** will be caught inside the slight indentation. Preferably, this slight indentation **44** will reduce the risk of the spinal needle **26**, the needle sleeve **27** and/or the stylet **28** (this assembly embodying herein at least one spinal tap assembly structured and arranged to tap into the patient to obtain a flow of cerebrospinal fluid), placed through the needle holes **25** in top shelf **22** and inside shelf **42**, sliding out of the test tube rack **21**, even if the test tube rack **21** is tilted at an angle. In addition, these two (preferably identical) needle holes **25** are arranged at both ends of the test tube holes **23** so that a physician using the test tube rack **21** might be comfortable using the test tube rack left-handed or right-handed. Preferably, the spinal needle **26** is an 22G3½ (1.27 mm x 8.89 cm Leur-Lok (TM) hub) spinal needle with a Quincke-type point, available through Becton-Dickinson, Franklin Lakes NJ 07417, reorder No. 405184.

With further reference to Fig. 1, the test tubes **24** typically have screw-on caps **31**. These screw-on caps **31** are connected to the test tubes **24** by flexible plastic tabs **32**. The

flexible plastic tabs **32** are attached to the test tubes **24** by rings **34** around the test tubes **24**. The test tubes **24** are preferably made of sterilizable, lightweight, plastic material. Test tubes **24** have markings **48** (see Fig. 3) illustrating one milliliter (ml) or one cubic centimeter (cc) increments (up to 8 cc or 8 ml) so that the physician collecting CSF can tell when 1 cc of fluid has been collected. The bottom ends of test tubes **24** have inverted cone-shaped (tip down) internal surfaces so that the test tubes **24** can be spun in a centrifuge, allowing solid materials to settle in the bottom of the tubes. Such test tubes **24** are preferably approximately 4 ½ inches long, approximately 5/8 inch in outside diameter, standard CSF tubes. These test tubes **24** are well known in the art and readily available from well-known sources.

Top shelf **22** is attached at each end to side panels **37**. Side panels **37** are preferably made of the same lightweight, clear (i.e. see-through) plastic used to make top shelf **22** and the rest of the structure of the test tube rack **21**, thus embodying herein that such holder comprises an essentially-transparent plastic material. Side panels **37** have internal surfaces **38** and external surfaces **39**. Preferably, integrally attached to the external surface **39** of side panels **37** is a handle shelf **40**. Preferably, handle shelf **40** wraps around one of the open sides **35**, making that open side the front **43** of the test tube rack **21**.

Alternatively, handle shelf **40** may preferably extend through the test tube rack **21**, contain four test tube holes in a row and two needle holes, aligned between top shelf **22** with its four test tube holes **23** and two needle holes **25** and inside shelf **42**, with its four test tube holes **23** and two needle holes **25**, so that test tubes **24** can pass through top shelf **22**, handle shelf **40** and inside shelf **42** before coming to rest against bottom shelf **41**. Handle shelf **40** is preferably shaped as shown so that a physician can hold the test tube rack **21** with a left hand on the left side **45** of the handle shelf **40** (left hand not shown), with a right hand **20**, on the right side **46** of handle shelf **40**, or with either hand from the front **47** of the handle shelf **40** (such shelf embodying herein a handle structured and arranged to assist single-hand manipulation of such holder by the medical professional during the collecting of the cerebrospinal fluid directly from such spinal tap into such CSF tubes, when held by such holder, in a continuing manner without the need to grasp any such CSF tube during the collecting). This handle arrangement also embodies a handle arrangement wherein such first and second vertical cavities are arranged along a horizontal longitudinal row, having a midpoint, of such holder, and such handle is essentially horizontal and symmetrical with respect to such midpoint, and wherein such handle comprises the furthest longitudinal horizontal extensions of such holder.

Top shelf **22**, inside shelf **42** and bottom shelf **41** are integrally attached to the internal surfaces **38** of side panels **37**. Preferably, the whole test tube rack **21**, including top shelf **22**, side panels **37**, handle shelf **40**, inside shelf **42** and bottom shelf **41** are all made in the same mold of the same see-through lightweight, sterilizable, disposable, medical grade plastic material. Less preferably, the test tube rack **21**, including top shelf **22**, side panels **37**, inside shelf **42** and bottom shelf **41** are all made in the same mold of the same see-through plastic material, with the handle shelf **40** being poured separately, in a separate mold, but using the same material. Preferably, handle shelf **40**, molded separately, can be attached to the rest of the test tube rack **21** by heat welding, gluing or other appropriate attachment method. Less preferably, any subset of the test tube rack **21**, such as the top shelf **22** and the handle shelf **40**, attached by side panels **37**, may be molded separately from any remaining subset of the test tube rack **21** (such as the inside shelf **42** and the bottom shelf **41**), attached by side panels **37**, and later connected together by heat welding, gluing or other attachment method. Separate molding of subsets of parts of the test tube rack **21**, although less preferable, may be necessary in such circumstances which, for example, make the molding and manufacturing process easier and less expensive.

Fig. 2 is a top view of the preferred embodiment of test

tube rack **21**. Fig. 2 illustrates the four test tube holes **23**, arranged in a row, sized to hold test tubes **24**, and also illustrates the two needle holes **25** sized to hold a spinal needle **26**, a needle sleeve **27** or a stylet **28** (see Fig. 1). Fig. 2 also shows a preferred size and shape of handle shelf **40**. Preferably handle shelf **40** is large enough so that a hand **20** (see Fig. 1), can hold the test tube rack **21** on the left side **45** of handle shelf **40**, on the right side **46** of handle shelf **40**, or on the front **47** of handle shelf **40**. The shape illustrated in Fig. 2 is preferable for the handle shelf **40**. Other shapes, including separate left and right wing handles, or a separate front handle, a square-shaped handle shelf, or more rounded shapes, may all be preferred under specific circumstances of cost, manufacture, use, etc.

Fig. 3 illustrates the test tube rack **21** containing a stylet **28** by itself, four test tubes **24**, and a spinal needle **26** containing a stylet **28** encased in its needle sleeve **27**, each passing through holes in top shelf **22** and inside shelf **42** (See Fig. 1), and resting against bottom shelf **41** (these descriptions embodying herein wherein such holder is structured and arranged to stably hold, when such holder is in an upright position, any element selected from the group consisting of a spinal needle, a spinal needle sleeve, a spinal needle stylet, a spinal needle sleeve holding a spinal needle, and a spinal needle sleeve

holding a spinal needle and a stylet). Inside shelf **42** is preferably arranged so that, when held in test tube rack **21** in this manner, the 1 cc marking **49** on the test tubes **24** can readily be seen by a person holding the test tube rack **21**. In other words, it is preferable that the physician can see when the test tubes **24** are filled with 1 cc (or 1 ml) of fluid when the test tubes **24** are contained in the test tube rack **21**.

Fig. 4 illustrates the first step -- assembling the equipment -- in the method of using the test tube rack **21** and system **19** of the present invention. The spinal needle **26** containing a stylet **28**, encased in a needle sleeve **27**, can preferably be removed from its sterile packaging and placed through its corresponding needle hole **25** (see Fig. 1) in the test tube rack **21**. The four test tubes **24** can preferably be removed from their sterile packaging, their lids **31** can be unscrewed, and they can be placed in their corresponding holes **23** (see Fig. 1). As an alternate preferred embodiment, the four test tubes **24** can be placed in the test tube rack **21** and then sterilized along with the test tube rack **21** and packaged together in one sterile packet. In other words, it is preferable that the test tube rack **21** containing the four test tubes **24**, with their screw-on caps **31** unscrewed (but attached to the test tubes by the plastic rings **33** and plastic tabs **32** described above) be sterilized and packaged

together in a single package. In that way, all the physician or other medical professional has to do to prepare for a spinal tap procedure is pull two sterile packages open (one for the needle, stylet and sleeve and one for the tubes and rack) and place the test tube rack **21** containing the open tubes **24** on the procedure tray. Alternately, the test tube rack **21** may preferably be placed in a sterile package alone.

As another alternate preferred embodiment, the test tubes **24**, the test tube rack **21** and the spinal needle **26** (along with the stylet **28** and the needle sleeve **27**) can be prepackaged and sterilized together -- i.e., the elements of system **19** in the condition shown and as illustrated in Fig. 4 -- so that the physician only has to open one package **70** to have all of these items ready to perform a spinal tap procedure. Prepackaging some or all of these necessary tools together, using this test tube rack **21**, decreases the amount of time necessary for the physician or other medical professional to spend setting up for a spinal tap procedure. These described prepackages embody herein a sealed internally-sterile package sealing such holder and such CSF tubes and further wherein such package further seals at least one such spinal tap assembly.

Fig. 5 illustrates a subsequent step in the method of using a preferred embodiment of the present invention. Once the physician or other medical professional has assembled all of the

equipment that will be necessary to perform the procedure, including the four test tubes **24** (see Fig. 4) and the spinal needle **26** with its stylet **28** is inserted through the spinal needle **26**, then the patient must be prepared. Typically, the patient is placed on his or her side, exposing his/her back **50**. The patient's back **50** is sterilized and the skin around the site **60** of insertion is numbed. In other words, the patient is "draped and prepped." Preferably, the spinal needle **26** (with the stylet **28** inserted through the spinal needle **26**), is inserted at site **60** between the patient's vertebrae, illustrated in Fig. 5 and discussed above.

Fig. 6 illustrates that, once the spinal needle **26** is inserted into the patient's back **50** and positioned correctly, the stylet **28** is preferably removed from the spinal needle **26**. Less typically, the spinal needle **26** may be inserted into the dural space without the stylet **28**. Some practitioners prefer not to use the stylet **28** at all. In that case, the preferable method described herein is modified only in that the stylet **28** is discarded when the sterile packaging containing the spinal needle **26** is opened.

Fig. 7 illustrates subsequent steps in the method of using the preferred embodiment of the present invention, showing the collecting of CSF **51** into a test tube **24** held in the test tube

rack **21**. Once the spinal needle **26** is inserted into a back **50**, and the stylet **28** is removed from the spinal needle **26**, as illustrated in Fig. 6, the stylet **28** can be placed (as shown in Fig. 7) into the test tube rack **21**, through a needle hole **25**. Once the stylet **28** is removed from the spinal needle **26**, CSF **51** flows through the spinal needle and drips from the proximal end **52** of the spinal needle **26**. The whole test tube rack **21** containing four open test tubes **24** (or three for a pediatric procedure) can preferably be conveniently placed (as by the physician's hand **20**, see Fig. 1) under the proximal end **52** of the spinal needle **26** to collect CSF **51**. When a sufficient amount of CSF **51** has been collected, as indicated by the markings **48** on the test tube **24**, the physician preferably simply moves the entire test tube rack **21**, so that the next unfilled test tube **24** is aligned under the proximal end **52** of the spinal needle **26**, inserted into the patient's back **50**. Fig. 7 also illustrates the preferable slight indentation **44** in the inside surface **54** of the bottom shelf **41** of the test tube rack **21** to assist in preventing the spinal needle **26**, or needle sleeve **27**, or stylet **28** from moving.

Fig. 8 illustrates another step in the method of using the preferred embodiment of the present invention, filling another test tube **24** with CSF **51**. Fig. 8 illustrates the test tube rack

21 containing four test tubes **24**, the stylet **28** and the needle sleeve **27**. This assembly **53** (the test tube rack **21** containing four test tubes **24**, the stylet **28**, and the needle sleeve **27**) is the preferable assembly **53** during collection of CSF **51**. The assembly **53** is preferably simply shifted a few centimeters in one direction or the other (depending on the handedness and preferences of the practitioner) so that the next test tube **24** is aligned underneath the proximal end **52** of the spinal needle **26** to collect CSF **51**.

Fig. 9 illustrates an additional step in the method of using the preferred embodiment of the present invention, filling the final test tube **24** with CSF **51**. Again, the assembly **53** is preferably simply shifted a few centimeters in one direction or the other (depending on the handedness and preferences of the practitioner) so that the final test tube **24** is aligned underneath the proximal end **52** of the spinal needle **26** to collect CSF **51**. Fig. 9 also illustrates that the inside shelf **42** of the test tube rack **21** is preferably aligned so that the 1 cc markings **49** on the test tubes **24** are clearly visible when the test tubes **24** are contained in the test tube rack **21**.

Fig. 10 illustrates a subsequent step in the method of using the preferred embodiment of the present invention, closing the screw-on caps **31** on the test tubes **24**. Once an appropriate amount of CSF **51** has been collected in each test tube **24**, the

stylet **28** is preferably re-inserted into the spinal needle **26** before the spinal needle **26** is removed from the patient's back **50**. It is preferable to re-insert the stylet **28** through the spinal needle **26** before removing the spinal needle **26** because it may assist in preventing leakage of CSF **51** after the spinal needle **26** is removed. Once removed from the patient's back **50**, the spinal needle **26**, containing the stylet **28**, may preferably be placed in the test tube rack **21**, through a needle hole **25**. Or, alternatively, if the stylet is not re-inserted through the spinal needle **26** before the spinal needle **26** is removed from the patient's back **50**, the stylet **28** may remain in place in the test tube rack **21** as shown in Fig. 10, and the spinal needle **26** may be placed into the needle sleeve **27** which is already inserted through a needle hole **25**. When the spinal needle **26** is replaced into the test tube rack **21** in either of these preferred ways, the danger of needle sticks is reduced. By replacing the spinal needle **26** in this way, the needle is placed in a predictable position, needle tip down, so that the physician or other medical professional who cleans up after the procedure is not faced with picking up a loose contaminated needle on a tray. Or, if the needle is placed back through the needle sleeve **27**, the physician or other medical professional avoids the potentially dangerous activity of trying to slide a needle, which has had contact with bodily fluids of a patient, into a needle sleeve **27**. Once the

spinal needle 26 is removed from the patient and placed into the test tube rack 21, the screw-on caps 31 of the test tubes 24 can preferably simply be screwed down onto the test tubes 24, creating a seal to prevent leakage or spillage of CSF 51 from the test tubes 24 as they are transported to a laboratory for analysis.

This described method embodies herein a method comprising the steps of: providing a CSF-tube holder having a handle and needle-holder to stably hold a spinal needle assembly; arranging at least three open CSF tubes in such holder; inserting a spinal needle containing a stylet between a patient's vertebrae until a tip of the spinal needle reaches a dural space; removing such stylet from such spinal needle; placing such stylet in such needle-holder of such holder; grasping such holder by such handle; placing such holder under the proximal end of such spinal needle so that CSF drips from such proximal end of such spinal needle into a first such open test tube; determining when such first open test tube contains a sufficient amount of CSF; shifting such holder so that CSF drips from such proximal end of such spinal needle into a second such open test tube; determining when such second open test tube contains a sufficient amount of CSF; shifting such holder so that CSF drips from such proximal end of such spinal needle into a third such open test tube; determining when such third open test tube contains a sufficient

amount of CSF; removing such stylet from such needle-holder; replacing such stylet inside such spinal needle; removing such spinal needle containing such stylet from the dural space; placing such spinal needle containing such stylet into such needle-holder; and closing such three open test tubes; and further comprising the steps of placing a needle sleeve into such needle-holder of such holder, and placing such spinal needle containing such stylet into such needle sleeve.

Although applicant has described applicant's preferred embodiments of this invention, it will be understood that the broadest scope of this invention includes such modifications as diverse shapes and sizes, materials and methods of manufacture. Such scope is limited only by the below claims as read in connection with the above specification. Further, many other advantages of applicant's invention will be apparent to those skilled in the art from the above descriptions and the below claims.